PRELIMINARY AMENDMENT AND RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS

Attorney Docket No.: Q111431

Application No.: 10/551,475

### REMARKS

## Status of the Claims

Claims 47-98 are all the claims pending in the application. Claims 48-55, 57, 59-60, 63, 69, 71-79, 83, 84, 87, 92-94, 97-98 are withdrawn from consideration as being directed to non-elected inventions. Claims 56, 58, 61-62, 80-82, 85, and 90 are canceled herewith. Claims 47-49, 59, 60, 63-68, 70, 71-78, 83, 87, 88, 89, 91, 92 are amended herewith. No new matter is added by way of this amendment. Claims 93-98 have been added herewith, wherein claims 93-94 and 97-98 are directed to non-elected inventions and have been withdrawn. New claims 95 and 96 are directed toward a compound, which is directed toward an elected invention, as described below. Exemplary written description support for claims 93-96 may be found in paragraphs [0061] – [0111] and [0115] of the corresponding U.S Patent Publication No. 2006/0211045. Exemplary written description support for new Claims 97 and 98 can be found at paragraph [0134] of the corresponding U.S Patent Publication No. 2006/0211045.

Entry and consideration of this amendment are respectfully requested.

#### Priority of PCT/GB04/01418 and U.S. Provisional 60/0465807

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority.

On page 2 of the Office Action, the Examiner further acknowledges Applicant's claim for foreign priority based on U.S. Provisional Application No. 60/465,807, filed on April 28, 2003, but notes that Applicants have not filed a certified copy of the U.S. Application as required by 35 U.S.C. § 119(b). In response, Applicants have amended the specification to make a specific reference to U.S. Provisional Application No. 60/465,807 as required under 35 U.S.C. § 119(e). Applicants do not believe that a certified copy of a U.S. Provisional application is necessary.

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On page 2 of the Office Action, the Examiner required that in view of the Applicant's extensive amendments to the claims between the international filing date of the 3/31/2004 and the national stage entry on 9/30/2005, Applicant provide priority dates for each new pending claims 47-92 as well as point out, specified as to page and line, where support under 35 U.S.C. § 112, first paragraph may be found in the present and earlier applications. Applicants traverse this requirement for at least the following reason.

The Examiner first bears the initial burden of presenting a *prima facie* case of unpatentability with regard to written description. *See In re Alton*, 76 F.3d 1168 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996). If the specification (or priority application) contains a description of the claimed invention, albeit not in *ipsis verbis*, then the Examiner in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient. *Id.* at 1175. The Examiner has not made such a *prima facie* showing, but rather has blanketly asked Applicants to submit a detailed showing of support under 35 U.S.C. §112, first paragraph. It is Applicant's position that such a request is improper without a *prima facie* showing of lack of written description support. Nevertheless, in order to expedite prosecution, Applicants have submitted a chart attached as Appendix A showing exemplary written description support in the priority application and the present application. The citation to the present application are from the paragraph numbers in the corresponding U.S. publication No. 2006/0211045 A1.

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# Response to Restriction and Election of Species Requirement

In response to the Restriction Requirement, dated December 22, 2008, Applicant elects Group IV, Claims 47, 64-68, 70, 88-91, drawn to a compound of formula 1. This election is made *with traverse*.

Applicants maintain that the inventions of Groups IV and I, II and V are not unrelated. Applicants respectfully submit that the claims in Groups I, II and V clearly possess unity of invention, as being linked by a special technical feature not disclosed in the prior art. Specifically, Applicants point out that Faye *et al.* (Biochemistry 30:5066-5075), cited to support a lack of unity of invention, do not disclose a compound of formula I comprising a red, near ir or blue dye, as is recited in instant Claim 64. This feature defines a novel contribution over the prior art, not disclosed in Fay *et al.* For this reason also, Applicants maintain that Groups I, II and V should also be examined on the merits in the instant application.

Specifically, with regard to Group V (claim 92), Group V is not unrelated to Group IV. To the contrary, the inventions of Groups IV and V are both directed to a compound wherein an optically active fluorescent ligand is present. In other words, the inventions of Groups IV and V are connected at least because they both employ a ligand and a fluorescent tag in a compound. Specifically, the compounds of Group V illustrate the classes of: a) xanthine-like adenosine based antagonists (ABA-BY 630/650-X), b) adenosine-like adenosine based antagonists (APEA-BY 630/650-X, ABIPEA-BY 630/650-X), c) beta-adrenoceptor agonists (salmeterol-BY 630/650-X, derivative salmeterol-BY 630/650-X, clenbuterol-BY 630/650-X), d) beta-adrenoceptor antagonists (CGP12177-BY 630/650-X, propranolol-BY 630/650-X, ICI118551-BY 630/650-X, alprenolol-BY 630/650-X).

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Furthermore, Applicants maintain that Claims 71, 73-77 is not unrelated to Group IV and should be examined on the merits. The Examiner has indicated that claim 71 is classified in Group II, directed to a process of preparing a library of tagged ligands. However, Claim 71 is directed to a compound claim, a fluorophore linker of formula V'. Moreover, the Examiner has indicated that Claims 73-77 are drawn to a method of selecting a tagged ligand. However, Claims 73-77 are directed to a library of fluorescent ligands of formula I or I'. Group IV and Claims 71, 73-77 clearly possess unity of invention, as being linked by a special technical feature not disclosed in the prior art (i.e., compound of formula I comprising a red, near ir or blue dye). For this reason also, Applicants maintain that Claims 71, 73-77, should also be examined on the merits in the instant application.

Applicants respectfully request that should the claims currently under examination be found allowable, Claims in Groups I-III and V should be rejoined. Claims in Group I-III and V recite a library or a process of preparing a library of tagged ligands, the methods containing all limitations of the allowed compound claims, and therefore should be rejoined as a matter of right should the product claims be found allowable.

Applicants reserve the right to file one or more Divisional Applications directed to nonelected subject matter.

#### Election of Species

The Examiner has identified the application as containing claims directed to more than one distinct species. Applicants thank the Examiner for conducting a telephonic interview on January 15, 2009, wherein Applicants requested clarification on the election of species requirement. The Examiner stated that within the Group elected, Applicants need to elect a

species of fluorescent ligand and a target. The Examiner believes claim(s) 47, 64-68, 70, 88-91 for Group IV are generic. Applicant has been advised that a response to this requirement shall include an identification of the species that is elected (in a chemical drawing) and a listing of all claims readable thereon.

In response to the Examiner's requirement, Applicant elects, *with traverse*, the the GPCR ligand and the red fluoresecent target for examination. Claims 47, 64-68, 70, and 88-91 are readable upon the elected species. The chemical drawing for the ligand and target are shown below, respectively:

and

Applicant submits that if any of the elected claims is found to be allowable, claims dependent therefrom should similarly be considered allowable in the same application. In the event the Examiner withdraws the restricition requirement for Groups I - III and V, Applicants request the Examiner to contact the undersigned attorney to elect a species in these Groups.

Finally, on page 8 of the Office Action, the Examiner requested Applicants to indicate what functional groups of the elected species of fluorescent ligand corresponds to which trade names, chemical names, and variables set forth in the readable claims. Applicants respectfully submit that the tradename BODIPY® 630/650 contains the following chemical formula:

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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